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Food Safety And Inspection Service
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AUDIT REPORT FOR NETHERLANDS

FEBRUARY 10 THROUGH FEBRUARY 28, 2000

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Netherlands Inspection Service for Livestock and Meat *(*RVV) system from February 10 through February 28, 2000. Eight of the 30 establishments certified to export meat to the United States were audited. Three of these were slaughter establishments; the others were conducting processing operations.

The last on-site audit of Netherlands inspection system was conducted in January 1999. Twenty-two establishments were audited: 19 were acceptable, and three were unacceptable (Est. 49, 189, and 410). The issues of concern for deficiencies at the time of the previous 1999 audit were:

1. Company-paid inspectors performed inspection procedures.
2. In 12 of 14 establishments audited, the postmortem inspection was incomplete. Postmortem inspection procedures for large calves, skinned calves and hogs were in variance, and did not meet U.S. requirements.
3. Boneless meat inspection was not done.
4. Dead on arrival (DOA) carcasses and condemned/inedible product was not denatured or decharacterized.
5. Processed product and freezer warehouse establishments were not required (RVV) to develop SSOPs. However, the establishments visited had prepared SSOPs as a part of QA-ISO 9000/HACCP plans. The establishments checked off deficiencies, but failed to document actual deficiencies and/or the corrective actions taken. Two warehouse/freezers audited did not conduct daily pre-operational and sanitation. Three establishments did not identify, prevent, or control direct product contamination during the audit, and were delisted.
6. Fecal contamination indicator is determined by testing *Enterobacteriaceae* and aerobic plate counts in lieu of generic *E. coli* testing (equivalent procedures). Of the14 slaughter establishments audited, one did not conduct testing; six did not collect samples randomly; eight failed to collect samples at required frequency; two collected frozen samples from variable sites; and six collected samples from 3-sites. The results were not charted or graphed using the 13 most recent sample results for process control. When maximum limits were exceeded, the establishments failed to document the process control and the corrective actions taken.
7. RVV did not mandate HACCP implementation in slaughter establishments and processed products, however, HACCP plans in 19 establishments were incomplete and/or being developed; in three establishments the plans were not developed; and in three establishments HACCP plans were available but not implemented. The establishments failed to record actual values and problems pertaining to process control and/or how the

processes were brought under control. The establishments also did not perform annual reassessment of the plans.
8. *Salmonella* species sampling and testing procedures did not meet FSIS requirements.
9. The government of the Netherlands does not perform species verification testing.

Except for the inadequate and incomplete large calves postmortem inspection procedures which do not comply with FSIS and EU procedures, failure to denature/decharacterize dead on arrival (DOA) carcasses, condemned/ and inedible products, failure to monitor arsenic residues in meat product, and species verification testing, all serious deficiencies cited above were corrected.

Product prepared from beef of Netherlands origin is not eligible for export to U.S. due to *bovine spongiform encephalopathy* (BSE). The pork product import is also restricted, and shall be cooked to internal temperature of 69° C due to hog cholera.

During the calendar year 1999, Netherlands establishments exported 12,299,985 pounds of canned hams, picnics, luncheon meats, chopped ham, and sausages to the United States. Port-of-entry rejections were 0.007% for pathological defects, and shipping marks.

PROTOCOL

The on-site review was conducted in four parts. One part involved visits with various Netherlands' meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. Sixteen U.S.-certified establishments were selected randomly for records. Of these, eight were pre-selected for on-site establishment visits. The third part was conducted by on-site visits to establishments. The fourth was a visit to two official laboratories performing analytical testing of samples for the national residue and microbiological monitoring program, and one private laboratory performing testing microbiological samples.

Program effectiveness determination focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation of Hazard Analysis and critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. The Netherlands' inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Based on the performance of the individual establishments, the Netherlands' "In-Plant Inspection System Performance" was evaluated as In-Plant System Controls in Place.

Effective inspection system controls were found to be in place at the time of on-site audits of establishments visited. However, the following serious inspection control deficiencies were noted following document audits, discussions with RVV, establishments, and laboratory officials/representatives:

- Continuous and direct (in-plant) inspection coverage in processed meat product and warehouse/freezer facilities was not being provided daily. Inspectors routinely visited these establishments at 4-weekly intervals and/or more frequently if necessary. Inspection coverage was also not provided during second or third shift operation establishments.

- Supervisory officials routinely do not conduct monthly in-depth reviews of the establishments. The details are discussed in the text.

- There is no official oversight of private laboratories.

- Monitoring for arsenic was not done in 1999. It was stated that arsenic testing 'surveillance' sampling would be included in the CY 2000 residue-testing program.

- All slaughter establishments visited had implemented PR/HACCP systems. The evaluation standard for aerobic colony counts in conjunction with *Enterobacteriaceae* values as a fecal contamination indicator standards requiring 'immediate corrective action' and /corrective action' were lowered. The change is discussed under 'Testing for *Enterobacteriaceae* in lieu of *E. coli*'.

- *Salmonella* species testing (FSIS recognized-equivalent procedure) was started in 9 of 12 currently U.S.-certified slaughter establishments in May 1999. On 1st and 2nd set-samples results (failing to meet performance standards), further testing was put on hold until March 2000. The details are discussed under 'Testing for *Salmonella* spp.' These changes, it was learned, had not been communicated to FSIS, IPD due to an oversight.

- RVV does not have a microbiological monitoring program for finished products, which includes 'schedule' or 'directed' testing (*Salmonella* and *Listeria)* for ready-to-eat product. However, the ready-to-eat products are periodically sampled by the establishments, and tested for *Salmonella* and *Listeria monocytogenes* in private accredited laboratories.

- Previously reported deficiencies for large calf's postmortem inspection procedure, and control of DOA carcasses, and condemned/inedible product by denaturing/decharacterization were not corrected.

- The Netherlands is not exempt from official species verification, and the establishment testing for species verification does not comply with FSIS requirements. This was a repeat deficiency.

Entrance Meeting

On February 10, an entrance meeting was held at Voorburgh at the RVV offices and was attended by J. van den Berg, Deputy Director RVV, Dr. M. Weijtens (VVM), Dr. A. Hom (WGA), and Ing. L. v. Duijn, Head RV Inspection Program, Dr. W.A.M. Jansen (RVV), Ing. G. Corstiaensen (meat industry representative), Mr. Chris Langezaal, FAS/U.S. Embassy, and Dr. Hussain Magsi, International Audit Staff Officer, FSIS. Topics of discussion included:

1. Animal health status.
2. Residue and microbiological monitoring.
3. Official oversight and enforcement
4. Consumer complaints and port of entry rejections.
5. Previous audit issues stated above.
6. Understanding of FSIS 'delistment and relistment' of establishments policy.

Headquarters Audit

As of January 2000, RVV has been reorganized. Mr. P. Cloo is the new RVV Director and Dr. J. van den Berg is the RVV Deputy Director.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be lead by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called 'the auditor") observed and evaluated the process.

The auditor conducted a review of the inspection system documents pertaining to the establishments listed for records review. This records review was conducted at RVV headquarters. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to the establishments that were certified to the U.S.
- Label approval records such as generic labels.
- New laws and implementation documents such as regulations, notices, directives, and guidelines.
- Sampling and laboratory analyses for residues.

- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs generic *E. coli* testing, and *Salmonella* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

Some of the concerns noted as a result of the examination of these documents have been discussed in the text.

Government Oversight

All inspection veterinarians and food inspectors in establishments certified by the Netherlands as eligible to export meat product to the United States were full-time or part-time employees, receiving no remuneration from either industry or establishment personnel. However, the inspection coverage was inadequate in certain situations discussed under 'Laboratory Audits', 'Animal Disease Controls', 'Residue Controls', 'Inspection System Controls', 'Testing for *Listeria monocytogenes'*, 'Species Verification Testing', and 'Monthly Reviews'.

Establishment Audits

Thirty establishments were certified to export meat products to the United States at the time this audit was conducted. Eight establishments were visited for on-site audits. In all eight establishments visited, both RVV inspection system controls and establishment system controls were in place, to prevent, detect and control contamination and adulteration of the product.

Laboratory Audits

The auditor visited two official laboratories and one private laboratory. The official laboratories visited were Central RVV Laboratory (CLRVV) in Wageningen and a regional DLRVV Laboratory in Assen, and the private laboratory was CCL in Veghel. The official laboratories are operated with public funds.

- Official Laboratories. The CLRVV develops and monitors 'National Plan for Residues in Live Animals and Animal Products' according to European Union (EU) mandated plan for specified substances. While developing an EU directed program, the laboratory also takes into account the nationally mandated and other clients (importing country) requirements. It analyzes hormones, veterinary drugs, and beta-agonistic compounds.

- The analyses of other required substances is shared by five official regional DLRVV laboratories located in Almelo, Amsterdam, Assen, Wageningen, and Weert. In addition, the laboratories perform routine microbiological testing for samples received from slaughterhouse inspectors. The DLRVV is Assen plans and conducts U.S.-required *Salmonella* species testing.

- Private Laboratories. In addition to Rikilt (DLO) Laboratory (national reference laboratory), there are several other private laboratories. Thirteen of the other private laboratories conduct meat and poultry analyses for several compounds and microorganisms, including *Enterobacteriaceae*, *Listeria*, *Salmonella*, microorganisms, and/or water. CLRVV contracts DLO to conduct testing for surveillance targeted compounds, environmental contaminants, and prohibited compounds.

During the laboratory audits, the emphasis was placed on the application of procedures and standards that were equivalent to the U.S. requirements. Information was collected on (1) government oversight of the accredited, approved, and private laboratories stated above, (2) inter-laboratory quality assurance procedures, including sample handling, and (3) methodology. The auditor also applied the following criteria established for use of private laboratories under FSIS's Pathogen Reduction/HACCP rule and evaluated laboratory system's performance.

The auditor determined that:

- A national accrediting body 'STERLAB' accredited all laboratories in the Netherlands. The STERLAB is accepted by the European Cooperative Accreditation (EA) multilateral agreement on mutual recognition of accredited bodies. The EN 45000.1 operational standards served as the basis for their work with ISO guidelines.
- The accredited private labs periodically consulted with RVV, and participated in national accreditation (STERLAB) deliberations. However, there was no oversight by RVV on private laboratories.
- In general, the laboratories followed accredited laboratory assurance programs, and demonstrated effective controls for sample handling, timely analysis, data reporting, tissue matrices for analysis, equipment maintenance and operations and printouts, minimum detection levels, recovery frequency, percent recoveries, sample compositing, and corrective actions. The methods used for analyses were standard or in line with EN 4500.1 guidelines.

Establishment Operations by Establishment Number

The following operations were being conducted in the establishments visited:
Canned hams, and sausages (Est. 19)
Pork slaughters, and cut up (Est. 27, 193)
Pork cut up, and bacon processing (Est. 98)
Pork cut up (Est. 124)
Canned hams, and cocktail sausages (Est. 139)
Calf slaughters, and cut up (Est. 369)
Freezer/warehouse, packaging (Est. 451)

SANITATION CONTROLS

Based on the on-site audits of establishments, the Netherlands' inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, hand washing facilities, sanitizers, separation of operations, pest control and monitoring, temperature control, lighting, work space, ventilation, maintenance and cleaning of over-product ceilings and equipment, dry storage areas, personal dress, habits and hygiene, equipment sanitizing, and product handling and storage.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic regulatory requirements.

ANIMAL DISEASE CONTROLS

With the exception listed below, the Netherlands inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures (swine) and disposition, and procedures for sanitary handling of returned and rework product.

1. The large calf postmortem inspection procedures did not meet U.S. requirements. The procedures were unchanged from those observed during previous audit in Netherlands. This is a repeat system deficiency.

During 1999 bovine tuberculosis (one case), *bovine spongiform ecephalopathy* (two cases), and bovine cysticercosis (prevalent – data not available) were reported by RVV. At the time of audit, information was not readily available on measures taken (animal trace back, animal ID, etc.) on the epidemiology.

RESIDUE CONTROLS

The Netherlands National Residue Testing Plan for 1999 was being followed. The CY 2000 program would be started in March 2000. The inspection system had adequate controls in place to ensure compliance and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

The Netherlands inspection system had adequate controls in place to ensure humane slaughter, and adequate product safety.

HACCP Implementation

All establishments approved to export meat products to the U.S. were required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instruments used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements.

Testing for *Enterobacteriaceae* in lieu of *E. coli*

The testing is being done according to FSIS recognized-*E. coli* testing equivalent *Enterobacteriaceae* testing program, which addresses sample collector, testing laboratories, indicator microorganisms, testing strategy, sampling sites, sampling tools, and analytical methods. The aerobic colony counts for pork carcasses used as "and, and/or" parameters, in conjunction with *Enterobacteriaceae* values as fecal contamination indicator were changed from average in log N/cm² 3.4 to N/cm ² 4.0 for 'Class I Action (requiring no immediate corrective action)', and average in log N/cm² >3.4 to N/cm² > 4.0 for 'Class II Action (requiring repeat hygienic measurement and/or action). This was a significant change. Data justifying these changes was not readily available and/or offered for audit.

All establishments at the time of audit demonstrated an adequate control in place to prevent meat products intended for Netherlands domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

Except as noted below, the RVV's inspection system controls for swine ante-and post-mortem inspection procedures and dispositions, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans) were in place and were effective in ensuring that products produced by the establishments were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

The following serious deficiencies were noted in all establishments:

- DOA condemned and inedible products were shipped off the premises without denaturing/ decharacterizing according to variable arrangements for shipping with the only rendering facility in Netherlands. These arrangements, the auditor determined, were not sufficiently reliable to ensure control of contaminated, adulterated, unsound or diseased carcasses or parts for being diverted to human supply food chain.
- Large calf postmortem inspection procedures are similar to small calf inspection. No change has been made to comply with U.S. requirements since previous FSIS visit.
- As a result of EU required HACCP-implementation in 1996/97, the inspection coverage/oversight frequency by official inspectors in EU and U.S.-certified establishments was reduced (except in slaughter operations) from daily to '4-week intervals'. Therefore continuous and direct inspection coverage, according for U.S. oversight procedures, in each operational shift is not provided in all establishments other than in slaughterhouses. Inspection and indepth monthly supervisory coverage required by FSIS is discussed under "Monthly Reviews".
- Lack of daily monitoring, and verification for SSOPs and HACCP implementation.in processed products, and warehouse/freezer facilities.

Testing for Listeria monocytogenes. In Establishments 19 and 129, which prepare ready-to-eat products, *Listeria monocytogenes* was not identified in their HACCP plans as a hazard likely to occur. Therefore, planned testing under HACCP is not done.

RVV does not have a microbiological monitoring program for finished products, which includes 'schedule' or 'directed' testing (*Salmonella* and *Listeria)* for ready-to-eat product. However, the ready-to-eat products are periodically sampled by the establishments, and tested for *Salmonella* and *Listeria monocytogenes* in private accredited laboratories.

Testing for *Salmonella* Species

The eight establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella.* Basic FSIS regulatory requirements were evaluated according to the criteria employed in U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

The Netherlands has adopted the FSIS regulatory requirements for *Salmonella* testing.

The *Salmonella* testing programs were found to meet the basic FSIS regulatory requirements.

The testing with FSIS recognized RVV-equivalent procedures for *Salmonella* were started in May 1999. Eight of 12 U.S.-certified establishments were included in the target plan. The *Salmonella* species test results were available in the establishments, and in the official Regional DRLVV laboratory in Assen. The samples were analyzed in Assen laboratory using ISO 6579, 3rd Edition method. The laboratory monitored the program.

The records audit results (as of 2/8/00) are summarized as below:

1. RVV Screening Program. Following initial screening eight establishments were included in the program in May 1999 at a frequency of monthly intervals. Six of 61 samples tested were positive. Other establishments were planned for screening in CY 2000.
2. RVV Target Program. The testing with FSIS recognized RVV-equivalent procedures for *Salmonella* were started in May 1999. Eight of 12 U.S.-certified establishments were included in the target plan.

One calf and three swine slaughter establishments failed to meet performance standards on completion of 1st set-series. Further testing was put on hold until March 2000.
Four swine slaughter establishments failed to meet performance standards, and took corrective actions, but failed 2nd test-series. Three of these reassessed their programs. Further testing was put on hold until March 2000.

It was stated that on completion of any of the series, starting March 6 (10th week), the sampling procedures would be changed to 'same as' U.S. sampling procedures (cork borer to sponging method).

Species Verification Testing

At the time of this audit, Netherlands was not exempt from the species verification-testing requirement and the auditor determined that species verification testing was not being done which does not comply with FSIS requirements. RVV did not sample or test for species identification. However, RVV monitors and verifies species identification sampling done by the establishments. Periodic samples were collected by the establishments, and analyzed by a government lab Rekilt-TNO.

Monthly Reviews

The internal review program was applied equally to both export and non-export establishments. Internal review visits were not announced in advance and were conducted during the export activity. The records of audited establishments were kept in the establishments and were routinely maintained on file for a minimum of two years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, it is delisted for U.S. export. Before it may again qualify for eligibility to be reinstated, the responsible supervisory officials conduct an in-depth review and the results are reported to RVV headquarters. The supervisor(s) in conjunction with the inspector-in-charge formulate a plan for corrective actions and preventive measures. The slaughter establishments are under continuous inspection and are in-depth reviewed at least monthly. However, official RVV inspection coverage of processing and warehouse facilities include:

- Four-weekly audits: Assigned official patrol inspectors visit each establishment at 4-week intervals and verify the implementation of HACCP critical control points (CCPs). Second or third shift operations are not inspected.
- Quarterly audits: National Management HACCP Team member visits these establishments 4-times annually and conducts in-depth audit of facilities and equipment.
- Biannual audits: National Management HACCP Team members (one to three) visit these establishments twice a year and audit randomly selected operations/processes, establishments areas/equipment, and establishment HACCP records.
- 3-yearly audits: National Management HACCP Team members (two to four) visit these establishments at three-year intervals, in-depth audit HACCP and establishment system programs, operations, and records.
- Special audits: National Management HACCP Team member visits U.S.-certified establishments at FSIS required monthly intervals.
- The inspectors also visit establishments to certify exportation for all shipment to any country, whenever needed.

Enforcement Activities

RVV provided official directive dated March 6, 2000, which describes RVV's Quality Management Program. The Quality Management group is responsible for internal enforcement activities.

- Consumer Complaint. In response to a consumer complaint concerning adulteration of fully cooked ready-to-eat DAK ham exported by Establishment 129 with a 'pin'. The Regional *Inspectorate* (*Inspectie W & W*) for the Ministry of Health Protection, Commodities and Veterinary Public Health (responsible for compliance enforcement) carried out an investigation at the product origin (Est. 129). The establishment HACCP and other production records were audited/investigated. It was concluded that it was a probable accident; the source or actuality could neither be denied nor established.

- U.S. Port-of-entry Rejection. With respect to yellow-coloring adulteration of hams received in establishment 129, the RVV's special investigation and compliance group (Inspectie V & V) conducted an investigation and through lab analysis determined that the non-meat additives (cure-mix) was adulterated with a forbidden industrial Sudan/Yellow DYE (1-(phenylazo)-2-napyhthalene. The product from the same batch was not available and could not be recalled or analyzed. The Ministry has not finalized the case.

- Labeling violation for cocktail sausage packed in brine was under investigation. The results were not available.

Exit Meetings

On February 23, an initial meeting was conducted in an establishment with Dr. J. van den Berg. An exit meeting was conducted in Voorburgh on February 28, 2000. The RVV participants were

Drs. Berg, Jansen, Dr. Ricjkert van der Flier (MVV), and other staff. Subjects of interest cited above were discussed.

Dr. Berg stated that RVV had initiated several actions to provide FSIS assurance with compliance enforcement. He stated that:

1. Calf slaughter postmortem inspection procedures were being discussed with EU. RVV would also consult the subject with FSIS.
2. Arsenic residue testing would be included in CY 2000 as in surveillance program
3. DOA carcasses condemned and inedible product handling procedures would be streamlined for uniform disposition. FSIS would be consulted.
4. The changes made on aerobic colony counts would be notified to FSIS, and that an oversight resulted in delayed communication.
5. FSIS required continuous inspection (daily inspection monitoring), and coverage of second third shift operations, including inspection coverage of processed products, and warehouse/freezer facilities at less than daily frequency was the result of EU-HACCP plan and negotiated agreement with the packers. It was also stated that the practice is being applied in all EU countries.

Dr. R. v. d. Flier stated that he would be travelling to visit FSIS, IPD staffs, and further discuss these and other issues.

CONCLUSION

The inspection system of the Netherlands was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Eight establishments were audited and all eight were acceptable. The deficiencies encountered during the on-site establishment audits were adequately addressed to the auditor's satisfaction. However, following serious deficiencies were observed:

- Reduced inspection control and establishment system monitoring/oversight from daily to monthly inspection visits in processed product and warehouse/freezer facilities and lack of second and third shift operation establishments inspection coverage is contrary to current FSIS regulations and policy.

- Required official supervisory in-depth audits are conducted.

- There is no official oversight of private laboratories.

- Monitoring for arsenic is not being monitored/tested.

- All slaughter establishments visited had implemented PR/HACCP systems. The evaluation standard for aerobic colony counts in conjunction with *Enterobacteriaceae* values as a fecal

contamination indicator standards requiring 'immediate corrective action' and /corrective action' were lowered. The change was not discussed with FSIS.

- *Salmonella* species testing (started in May 1999). Following 1st and 2nd set-samples results failing the performance standards, further testing was put on put hold until March 2000.

- RVV does not have a microbiological monitoring program for finished products, which includes 'schedule' or 'directed' testing (*Salmonella* and *Listeria)* for ready-to-eat product.

- Previously reported deficiencies for large calf's postmortem inspection procedure, control of DOA carcasses, and condemned/inedible product by denaturing/dechracterization were not corrected.

- Verification sampling for species identification is not done by RVV. Netherlands is not exempt from official species verification. This is also a repeat deficiency.

(signed) Hussain Magsi, DVM, MS
Hussain Magsi, DVM, MS
International Audit Staff Officer

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *Enterobacteriaceae* testing in lieu of generic *E. coli*.
D. Data collection instrument for *Salmonella* testing
E. Laboratory audit forms
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of the establishments visited on-site were evaluated as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. Sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
19	√	√	√	√	√	√	√	√
27	√	√	√	√	√	√	√	√
98	√	√	√	√	√	√	√	√
124	√	√	√	√	√	√	√	√
129	√	√	√	√	√	√	√	√
193	√	√	√	√	√	√	√	√
369	√	√	√	√	√	√	√	√
451	√	√	√	√	√	√	√	√

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

55	√	√	√	√	√	√	√	√
*82	√	√	√	√	√	√	√	√
153	√	√	√	√	√	√	√	√
*236	√	√	√	√	√	√	√	√
242	√	√	√	√	√	√	√	√
*378	√	√	√	√	√	√	√	√
505	√	√	√	√	√	√	√	√
515	√	√	√	√	√	√	√	√

*The establishment system documents were not presented by the companies at the headquarters due to 'company policy', and/or propriety reasons. The documents were audited at one their sister establishments.

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
1. The HACCP plan was validated using multiple monitoring results.
2. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. actions are described	9. Plan validated	10.Adequate verific. procedures	11.Adequate documentation	12. Dated and signed
19	√	√	√	√	√	√	√	√	√	√	√	√
27	√	√	√	√	√	√	√	√	√	√	√	√
98	√	√	√	√	√	√	√	√	√	√	√	√
124	√	√	√	√	√	√	√	√	√	√	√	√
129	√	√	√	√	√	√	√	√	√	√	√	√
193	√	√	√	√	√	√	√	√	√	√	√	√
369	√	√	√	√	√	√	√	√	√	√	√	√
451	√	√	√	√	√	√	√	√	√	√	√	√

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

55	√	√	√	√	√	√	√	√
*82	√	√	√	√	√	√	√	√
153	√	√	√	√	√	√	√	√
*236	√	√	√	√	√	√	√	√
242	√	√	√	√	√	√	√	√
*378	√	√	√	√	√	√	√	√
505	√	√	√	√	√	√	√	√
515	√	√	√	√	√	√	√	√

*The establishment system documents were not presented by the companies at the headquarters due to 'company policy', and/or propriety reasons. The documents were audited at one of their sister establishments.

Attachment C

Data collection instruments for *Enterobacteriaceae* testing

Each establishment was evaluated to determine if *E. coli* or equivalent testing requirement were met according to the criteria employed in the U.S. domestic inspection program. However, the aerobic colony counts testing in conjunction with *Enterobacteriaceae* values as fecal contamination indicator were changed from log N/ cm^2 3.4 to 4.0 for class I (requiring no immediate corrective action), and log N/ cm^2 > 3.4 to > 4.0 for class II (requiring a corrective action). It was stated that FSIS was not informed of the change due to an oversight.

Following information was collected.

1. The establishment has a written procedure for testing for generic *Enterobacteriaceae.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
27	√	√	√	√	√	√	√	√	√	√
193	√	√	√	√	√	√	√	√	√	√
369	√	√	√	√	√	√	√	√	√	√

Data Collection instruments for *Salmonella* spp. Testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were being met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) are being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations *
27	√	√	N/A	√	√	*
193	√	√	N/A	√	√	*
369	√	√	N/A	√	√	*

* *Salmonella* species testing (FSIS recognized-equivalent procedure) was started in 9 of 12 U.S.-certified slaughter establishments in May 1999. Testing was terminated in two establishments, which failed the 2nd test-series. Using 'same as' U.S. sampling procedures, on March 6, 2000 the sampling would be resumed in these and other establishments, which would have completed the first or second target (test-series) testing.